# HEALTH CANADA

# THERAPEUTIC PRODUCTS PROGRAMME

# STRATEGIC FRAMEWORK

# FOR

# 1998-2001

**This document is designed to provide the management and staff of the Therapeutic Products Programme with the strategic guidance required to ensure that Canada continues to enjoy one of the most effective regulatory regimes in the world.**

**Revised August 1998**

## PREFACE

The Therapeutic Products Programme exists to protect the health and safety of Canadians. Our vision is to be one of the most effective and efficient regulators of therapeutic products and controlled substances in the world. We cannot possibly become that and maintain our position if we do not attract and keep the best qualified and most motivated people and if we do not focus the thoughts and actions of those people in a common direction.

Over the last several years, all staff have been involved in an energetic and comprehensive re-engineering of the Therapeutic Products Programme, through their day-to-day activities, through participation in special initiatives, and through the general strategic planning process of the Programme. With the introduction of our Quality Improvement Initiative, this important work continues.

This document - our Strategic Framework - is the foundation of that strategic planning process and provides the strategic guidance that management, staff, and advisors need to drive towards the accomplishment of our mission and vision.

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# PROGRAMME DIRECTION

## 1. MISSION

To ensure that the drugs, medical devices and other therapeutic products available in Canada are safe, effective and of high quality and that narcotic and restricted substances are controlled in an effective and efficient manner.

## 2. VISION

- To be recognized as the national authority for the management of the benefits and risks of products intended for therapeutic use in Canada,
- To be respected worldwide as one of the most effective national agencies in drug and medical device regulation, and
- To be a national and international partner in the management of controlled drugs and substances.

## 3. MANDATE

### 3.1. AUTHORITIES

The mandate of the Therapeutic Products Programme is derived from several Acts of Parliament including:

- The Department of Health Act
- The Food and Drugs Act and the Drug and Medical Device Regulations
- The Controlled Drugs & Substances Act & Regulations
- The Industrial Hemp Regulations
- The Pest Management Control Act and Regulations
- The Patent Act & Regulations
- The Broadcasting Act & Regulations
- The Canadian Environmental Protection Act
- The Access to Information and Privacy Acts
- The Financial Administration Act and Regulations

In addition, Canada is a signatory to the Single Convention on Narcotic Drugs (1961); the Convention on Psychotropic Substances (1971); and the UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988) (The Vienna Convention); as well as the North American Free Trade Agreement and the General Agreement on Tariffs and Trade. These agreements may affect and constrain the Programme's regulatory activities or require actions to fulfil international obligations.

## 3.2. REGULATORY SCOPE

The prime responsibility of the Therapeutic Products Programme is the regulation of therapeutic, preventative and diagnostic products in Canada. The terms "drug" and "medical device" are defined in the ***Food and Drugs Act***, and are provided in Appendix A for reference. A working definition of "therapeutic product" is also included in Appendix A.

The definitions in the ***Food and Drugs Act*** cover a broad range of products:

**Pharmaceuticals**

- Prescription
- Non-prescription or over-the-counter including low risk products, e.g. sun-screens, antiperspirants, toothpaste, etc.

**Natural Health Products**

- Homeopathics
- Herbals
- Nutraceuticals

**Biologicals**

- Vaccines
- Blood and blood products
- Hormones and enzymes
- Allergenic extracts
- Tissues and organs
- Biotherapeutics, e.g., recombinant DNA products, genetically engineered products, etc.

**Radiopharmaceuticals**

**Medical Devices**

- Medical and dental implants
- Medical equipment and instruments
- Test kits for diagnosis
- Contraceptive devices

**Disinfectants**

## 4.0 STRATEGIC OBJECTIVES

The mission and vision of the Therapeutic Products Programme are achieved by focussing on the following strategic objectives:

- To ensure Canadians have timely access to safe, effective, high quality therapeutic products; are not put at undue risk by the use of therapeutic products available on the Canadian market; and receive appropriate information about the risks and benefits of those therapeutic products.

- To provide proactive legislative, policy, and operations support for law enforcement activities in the control of illicit drugs and related substances.

- To ensure the regulatory system in Canada is innovative, responsive to its environment, and conducive to the timely introduction of effective therapeutic products into the Canadian market; is developed with the full participation of clients, stakeholders and the public; and provides national and international leadership in therapeutic product regulation.

- To provide a work environment that enhances creativity and productivity and maximizes employee satisfaction.

## 5. KEY RESULT AREAS

To accomplish its strategic objectives, the Therapeutic Products Programme must achieve results in the following areas:

- **Safe and Effective Products of High Quality** - therapeutic, preventive and diagnostic products under the control and influence of the Programme are regulated in accordance with the Risk Management Framework.

- **International Leadership and Credibility** - the Programme is recognized for its leadership and work in partnership with other international regulatory agencies to improve and facilitate international regulatory harmonization and cooperation.

- **Controlled Drugs & Substances**—the Programme plays a proactive role in the identification and control of narcotic, restricted, and psychotropic substances in Canada and internationally.

- **Information Management and Dissemination** - information is developed and disseminated to stakeholders in a comprehensive and effective manner.

- **Client/Stakeholder Satisfaction** - client and stakeholder needs are met with the provision of timely, quality services through an efficient and responsive operation operating under the principles of fairness, equity, and transparency.

- **Efficiency and Responsiveness** - internationally competitive performance standards are set to meet stakeholders' needs in all activities and met.

- **Resource Management and Utilization** - funding is commensurate with the job to be done and an environment is created for effective resource management leading to increased efficiency, employee commitment and high morale.

- **Human Resources** - staff members are confident, highly trained, appreciated and recognized, and perform enthusiastically to ensure client satisfaction in a work environment that is flexible and meets their needs and concerns.

The achievement of these goals will have a positive **impact** on Canadian society by ensuring that:

- safe, effective, high quality therapeutic products are accessible to and used appropriately by Canadians;

- a regulatory environment conducive to research and development exists in Canada;

- the adverse health impact related to availability and misuse of drugs subject to abuse is reduced;

- the regulatory system contributes to an efficient and affordable health care system in Canada; and

- the regulatory system facilitates the competitiveness of the therapeutic product industry in the Canadian market and the Canadian therapeutic product industry in the world market.

## 6. STRATEGIC PRIORITIES - 1998-2001

- **Organizational Status** - to determine the most appropriate and effective mechanism for delivering the Therapeutic Products Programme.

- **Communications** - to develop and implement a communications strategy for internal and external communications.

- **Legislative and Regulatory Review** - to review existing legislative and regulatory frameworks and to develop an integrated, responsive, efficient, and effective legislative foundation for the work of the TPP; and to develop and implement specific new regulatory frameworks for various areas of responsibility.

- **Transition to Quality Management** - to implement Quality Management consistently throughout TPP.

- **Partnerships** - to develop and implement an international strategy to facilitate Programme delivery and to involve the public more effectively in Programme delivery.

- **Programme Structure and Delivery** - to continue the application of total quality improvement principles and practices and to optimize each of the Programme's processes and operations.

- **Resource Management** - to continue to work towards optimal resources for TPP, in the areas of funding, human resources, and accommodation.

- **Information Management** - to develop and implement an effective and efficient information management strategy to support Programme delivery.

## PROGRAMME CULTURE & PHILOSOPHY

### 7. GUIDING PRINCIPLES

As we work together to address our mission and objectives, we are committed to:

- Conducting our business in accordance with the principles and practices of **quality management**;

- Providing **responsive, value-added service** to the public, the Minister, industry and others involved in the health care field;

- Developing and maintaining a **responsible** regulatory framework through proactive, open and responsive consultative processes involving all affected parties, and by considering the costs of options proposed as well as their effectiveness;

- **Respecting the public and stakeholder trust** in the efficient use of human and financial resources;

- Conducting and promoting **risk/benefit** assessment and management;

- Maintaining a **sound scientific foundation** as a basis for regulatory decision-making;

- Strengthening our **leadership** role in the development and adoption of effective drug and medical device assessment methodologies and practices;

- Working in **partnerships** with provincial, national and international agencies engaged in drug and medical device assessment and control;

- Maintaining and promoting **timely communication**, inside our organization and with our stakeholders; and

- Creating an **effective and harmonious work environment.**

## 8. CODE OF CONDUCT - VALUES & POSITIVE BEHAVIOURS

The Therapeutic Products Programme believes in the fundamental principle that people are an organization's most important resource. In support of this principle, we have developed a Code of Conduct which is linked to our human resource policies and is intended to establish appropriate behaviours among ourselves, stakeholders, and clients. The present version was developed at a management meeting and, as an inherent component of our Strategic Framework, it has also been the subject of consultations with staff members throughout the Programme.

This Code of Conduct applies to every employee of the Programme and covers all interactions between employees, stakeholders, and clients including oral, written, and electronic (e-mail/Internet) communication.

All employees of the Therapeutic Products Programme are personally responsible and will be held accountable for creating and fostering a work environment in which the following values and positive behaviours are maintained and acknowledged on an on-going basis:

- **Dignity and Respect** - we will

  - Treat all employees, clients and stakeholders with dignity and respect at all times;
  - Ensure that employees are aware of the expected standard of behaviour;
  - Encourage, permit and value creativity;
  - Actively take steps to ensure that the workplace is free of discrimination, conflict of interest, prejudice, harassment and any other unacceptable behaviour; and
  - Recognize and directly challenge inappropriate behaviour and ensure timely and appropriate resolution.

- **Fairness, Equality and Compassion** - we will

  - Demonstrate fairness, equality and compassion in dealing with all employees.

- **Diversity** - we will

  - Recognize, accept, respect and value diversity;
  - Respect differences in others such as culture, beliefs, customs, values, opinions, education, language and gender; and
  - Encourage the creation and use of diverse work teams, committees and groups.

- **Openness and Honesty** - we will

- Ensure open, honest, transparent and timely communication; and
- Listen to others and be understanding.

- **Integrity** - we will

  - Be familiar with and exercise responsibilities concerning relevant Human Resource legislation, policies, regulations, directives and practices;
  - Be role models and ensure actions that match words; and
  - Demonstrate consideration, sensitivity, trust, cooperation, flexibility, and respect for confidentiality.

- **Health and Safety** - we will

  - Value and respect the need for employees to balance work, personal, family and community lives; and
  - Take appropriate steps to ensure a safe and healthy work environment.

The effectiveness of this Code of Conduct will be evaluated on a regular basis in conjunction with the annual, consultative review of the Strategic Framework and any required training and information sessions will be arranged as appropriate.

## 9. REGULATORY PHILOSOPHY & PRINCIPLES

The **primary function** of the regulatory system for therapeutic products in Canada is to protect and improve the health and safety of Canadians. Other important functions include facilitating economic development and industry competitiveness, enhancing Canada's research capacity, decreasing health care costs, and increasing the effectiveness of the health care system.

The **regulatory philosophy** of the Therapeutic Products Programme is to intervene no more than is required to accomplish our mission, but certainly no less. However, when we intervene, our activities must add value to the regulatory process through the development of critical information and then the communication of this information to decision-makers in all sectors, i.e., the provinces, health professionals, researchers, law enforcement agencies, industry, patients and the public. Our regulatory philosophy is based on the successful operation of two principles:

**Risk/Benefit Assessment and Management**

The regulatory framework in Canada is based on the principle of risk/benefit assessment and management. Risk management includes a range of strategies and related activities—for

example, a free market strategy that ensures proper information is available to the public; activities that promote education and community action by providing information and expertise to facilitate informed decision-making; and regulation that includes all forms of statutory action, e.g., rules of conduct, inspection, licences, enforcement and compliance action, etc.

The use of most drugs, medical devices, and other therapeutic products entails risks and benefits. The regulatory process is designed to ensure that sufficient information is generated throughout the process to enable effective, timely decisions concerning each product and its rational use. While Health Canada encourages voluntary regulation on the part of stakeholders, we must analyze, assess, decide on strategies, undertake activities and make sound scientific regulatory decisions according to the risks/benefits of each individual situation.

We will make every effort to ensure that legal agents are informed of their responsibilities to sell only safe and effective drug products. When this is not the case, the Programme will take appropriate action to protect the public from the risks posed to their health. We will carry out such actions in a consistent manner and on an equitable basis across Canada.

**Shared Responsibility**

The regulatory process is designed to enable the Programme to gather and/or develop knowledge efficiently, and to make it available in a timely fashion to all decision-makers. However, this process also recognizes the principle of shared responsibility by other partners involved in the development and use of therapeutic products, i.e., provincial and territorial governments, health professionals, researchers, industry, and the public.

A constructive regulatory framework defines the responsibilities of each partner in order to facilitate the free flow of information so that partners can make informed decisions. The framework also allows for the delegation of activities to third parties, through contracts or accreditation, to reduce overlap or duplication of effort.

While Canadian regulators continuously review and learn from experiences and the best practices of other systems, the regulatory system as a whole must be designed to meet the needs of Canadians within the context of the Canadian health system, Canadian medical practices and Canadian values.

## 10. PROGRAMME APPROACH

The regulation of therapeutic products and the delivery of associated services in Canada must be built on a strong foundation of intelligent programming, sound science, full and open communication, constructive partnerships and an efficient, productive organization culture following quality management principles.

**Intelligent Programming**

Canada's Therapeutic Products Programme has two important functions:

- To evaluate the safety, effectiveness and quality of therapeutic, preventive and diagnostic products available to Canadians; and

- To provide legislative policy and to support law enforcement activities in the control of illicit drugs.

The Programme addresses not only the safety of the therapeutic product *per se*, but also the claims being made about it as well as its ability to satisfy those claims.

The Programme is designed to be in step with, and enhance, the development process of regulated products. It tracks the stages in the life cycle of each product and addresses each stage of the cycle in an intelligent fashion. The Programme also allows for special access to a product at various stages if such a step is in the best interest of Canadians.

The Programme provides safety nets by acknowledging the imperfection of human endeavours and establishing adequate monitoring and recall processes. When Canadians are placed at risk, the system must respond quickly to minimize the impact of that risk. Therefore, the Programme must have mechanisms in place for monitoring adverse reactions and problem reports, ensuring post-approval surveillance and managing recalls and removals.

The Programme must be efficient and we must set realistic service standards for all processes, measure performance against those standards, communicate the results openly and make changes in a timely fashion.

An effective regulatory programme makes use of expertise outside of the organization. We have established expert advisory committees and set up an efficient and organized process by which these committees can provide input and advice at appropriate stages in our decision-making.

**Sound Science**

The Programme is committed to applying evidence-based decision-making as a basis for scientific risk/benefit management and policy development. Scientific information generated by stakeholders, in-house research, and contract work will address gaps critical in managing the risks presented by new substances and methods of delivery or targeting.

By maintaining a strong capacity to access, create and evaluate scientific evidence, the Programme will remain a major player in the move to harmonize the technical requirements for product review through participation in international scientific committees. Networking among scientific specialists will help us meet critical information needs, advance knowledge that will protect the Canadian public, and sustain the competitive science and technology capacity of the Programme and the country.

**Full and Open Communications**

Our primary role is to ensure that therapeutic products available in Canada are safe, effective and of high quality. Since risk/benefit management depends on timely communication and accurate information, communication will be one of our principal tools in achieving our mission. The Programme encourages timely, open communication between management and staff, and with outside organizations such as other sectors of Health Canada and the federal government, stakeholders and clients.

Effective communication improves the Canadian public's understanding of our role and functions. Therefore, we will continue to support and develop our use of communications technology by employing a wide variety of mechanisms to communicate with our clients, stakeholders and Canadians.

The Programme has also adopted the following basic principle: that within the parameters of the Access to Information Act, information should be made available to facilitate the public's ability to make informed decisions. All sections of the Programme will support and promote open, transparent decision-making and continue to enhance the quality of our processes through the free exchange of ideas.

**Constructive Partnerships**

The Programme supports the regulatory philosophy of shared responsibility. We recognize that others have an interest in assuring that drugs and medical devices available to Canadians are safe, effective, of high quality, and contribute to an efficient health care system. We also recognize there are other scientists and agencies around the world with important expertise who share our interests and goals. Therefore, one of our key roles in the health care system will be the formation and support of domestic and global partnerships.

In Canada, other national agencies involved in the assessment and control process of drugs and medical devices include the Patented Medicine Prices Review Board, the Canadian Coordinating Office of Health Technology Assessment (CCOHTA), the Solicitor General and the RCMP, and Revenue Canada. In the provinces, there are drug benefit programmes, licensing bodies, and law enforcement agencies. Around the world, there are many agencies engaged in the assessment and control of legal drugs, medical devices, and illicit drugs. We will work closely with these groups to ensure greater harmonization and less duplication of activities and a smooth flow of information.

Canadian health care researchers, workers and practitioners are professionals who are interested in the well-being of Canadians. In addition, health care professionals in other countries have objectives and goals that are often similar to ours. We have developed, and will continue to develop, mutually beneficial partnerships and shared ventures with such individuals in industry, associations, academia, other levels of government and other countries.

Consumers also have an important role to play in our health care system. We will work with them and their associations to ensure that therapeutic products are effectively evaluated, and that appropriate information is available to those who wish to make informed decisions about their health care.

**Productive Organizational Culture**

The Programme is committed to attracting, involving, and developing staff of the highest calibre. To ensure a creative and supportive environment, all members of the Programme will seek out ways to recognize and acknowledge excellence, ensure that accountability is commensurate with responsibility, and encourage creativity and the free exchange of ideas.

We embrace the philosophy of participatory management, whereby employees are empowered and involved in the decision-making processes that affect them. We are seeking to create an environment that enables staff and stakeholders across Canada to acknowledge each other's roles and contributions, and to work together effectively to protect and further the health and safety of Canadians.

## PROGRAMME MANAGEMENT

### 11. BUSINESS LINES & PERFORMANCE STANDARDS

Our business is the risk/benefit management of therapeutic, preventive and diagnostic products in Canada. The following business lines and their associated key activities form the basis for operational planning and the assignment of organizational responsibilities within the Therapeutic Products Programme:

- **Product licensing** - including pre-market authorization and post-market surveillance.
- **Establishment licensing** - including Good Manufacturing Practices (GMP) inspection.
- **Controlled substance surveillance** - including Drug Analysis Service.
- **Programme support** - including policy, planning, and management support services.

One of the critical success factors for our Programme is that we have performance standards for each of our activities, and that these standards be well-defined, realistic, internationally competitive and achieved.

Performance standards are essential to the well-managed organization for several reasons:

- to determine the exact nature and efficiency of the processes in place;
- to determine the adequacy of the resources applied to those processes;
- to indicate opportunities for corrective action;
- to indicate reasonable expectations for Programme processes; and
- to serve as targets for the enhancement of service.

The establishment and implementation of performance targets have been crucial to the past success of the Drugs and Medical Devices Programmes. To succeed in the future, we must refine existing targets and develop new targets in all areas of activity so that we and our clients will be better able to compare our standards and performance with those of similar regulatory agencies. Defined standards will also provide the management information that we need to

further refine our processes and resources. Meeting performance standards is critical in allowing us to set fees that are accurate and acceptable to our clients as part of our cost-recovery initiative.

Therefore, in keeping with our commitment to quality management principles and to the Government's service standards initiative, we have developed, and will continue to develop, performance standards for processes within each Programme element. Such standards will include quantitative and qualitative descriptions of the services we provide.

## 12. ORGANIZATIONAL STRUCTURE

### 12.1 Organizational Principles

In developing an organizational structure for the delivery of activities, the Programme has established the following principles:

- Form should follow function, and like activities should be consolidated, wherever possible, to form critical mass and to enable specialization.
- The resulting structure should enable the assignment and assumption of clear accountabilities.
- The resulting structure should facilitate a clear understanding of the role, responsibilities and functions of each unit. While each unit should have access to the resources it needs to fulfil its responsibilities, it does not have to "own" those resources.
- Assignment of responsibilities should follow the business activity lines currently in place or under development.
- All units should be designed to provide an appropriate level of service to other units, facilitating the team approach whenever possible, within and across organizational units.
- Geographically dispersed operations should be structured to support equivalent service delivery with equivalent management and administrative requirements.

### 12.2 Organizational Responsibilities

The organizational responsibilities for the Therapeutic Products Programme will be as follows:

- **Director General's Office (DGO)**
  - Line and functional management of the Programme.

- Development and management of the Programme's strategic and operational planning systems.
- Development and coordination of national liaison activities, Programme-wide communications and the Quality Management System.
- Development and coordination of Programme cost recovery activities.
- Development and provision of Programme management and administrative services.
- Coordination of Programme information technology support activities.
- Coordination of Programme information management planning and implementation.
- Management of a continuing education Programme.
- Management of Programme correspondence and briefing material.

- **Bureau of Pharmaceutical Assessment (BPA)**

  - Management of clinical trial review, pre-market review, licensing and research projects for pharmaceuticals.
  - Provision of pre- and post-market review services.
  - Management of the Special Access Programme for drug products.
  - Management of disinfectant review and licensing.

- **Bureau of Biologics and Radiopharmaceuticals (BBR)**

  - Management of clinical trial review, pre-market review, licensing and research projects for biological and radiopharmaceutical drugs.
  - Provision of pre- and post-market review services.
  - Provision of pre- and post-market laboratory support and research services.

- **Medical Devices Bureau (MDB)**

  - Management of clinical trial review, pre-market review, licensing, research projects, and post-market assessment of medical devices.
  - Management of the Special Access Programme for medical devices.
  - Provision of pre- and post-market laboratory support for medical devices.

- **Bureau of Drug Surveillance (BDS)**

  - Management of post-market surveillance activities to monitor the risks and benefits of marketed drugs.
  - Management of re-assessment and re-licensing for all drug products.
  - Management of advertising regulation for drug products.
  - Management of the Controlled Drugs and Substances Programme.
  - Management of the Industrial Hemp Programme.

- Management of research projects related to post-market assessment and controlled substances.

- **Bureau of Policy and Coordination (BPC)**

  - Management and coordination of Programme policy development, including the processing and interpretation of regulations.
  - Management of the policy development process.
  - Management of performance monitoring and reporting systems.
  - Development of Programme international strategies and policies and coordination of international activities.
  - Coordination of Programme research planning and review processes, and management of designated research projects.
  - Provision of scientific advice and coordination of expert advisory committees and scientific appeal processes.
  - Management of designated Programme support services including Access to Information.

- **Bureau of Compliance and Enforcement (BCE)**

  - Management of review and licensing processes for drug and medical device establishments.
  - Implementation and management of Mutual Recognition Agreements concerning establishment licensing.
  - Management of investigation and enforcement strategies and activities related to the manufacture, importation and sale of violative marketed products.
  - Provision of pre- and post-market laboratory analysis support services to Programme activities, as required.
  - Management of research projects related to compliance and enforcement.
  - Liaison with other government organizations related to investigation and enforcement activities.
  - Management of regional information dissemination.

- **Drug Analysis Service (DAS)**

  - Management of an analysis service for narcotic and illicit substances.
  - Management of research related to controlled substance analysis.
  - Liaison with other government organizations dealing with controlled substance use.
  - Support to harm reduction efforts.
  - Provision of intelligence on profiles, characteristics and prevalence of controlled substances based on analytical findings.

## 13. MANAGEMENT & ADVISORY COMMITTEES - TERMS OF REFERENCE

### 13.1 Programme Management Committee (PMC)

To function as the principal decision-making body for policy and strategic direction within the Programme and to provide the leadership necessary to achieve the Programme's mission and vision in an efficient and effective manner. To assist in this endeavour, the PMC has created a number of subcommittees, each chaired by a member of the PMC:

- **Subcommittee on Planning (PMC-PLAN)** - to advise on the Programme's issues and priorities relating to strategic and operational planning.

- **Subcommittee on Policy (PMC-P)** - to advise on the Programme's policy and regulatory framework and on the policies, guidelines and other guidance documents needed to support Programme operations.

- **Subcommittee on Research (PMC-R)** - to develop and maintain a strategic framework under which research is conceived, planned, conducted and reviewed to ensure that such research is directed towards enhancing the scientific base necessary for assessing risks/benefits, developing policies, guidelines and regulations, and for making decisions.

- **Subcommittee on Compliance (PMC-C)** - to advise on matters related to compliance, including surveillance, risk management and enforcement activities.

- **Subcommittee on Continuing Education (PMC-CE)** - to advise on continuing education plans, activities, guidelines and policies within the Programme.

- **Subcommittee on Informatics (PMC-I)** - to advise on information management and technology initiatives, activities, guidelines and policies.

- **Subcommittee on Communications (PMC-COMMS)** - to advise on communications and marketing activities designed to enhance the Programme's image and increase its identity among target audiences.

- **Subcommittee on Human Resources (PMC-HR)** - to advise on a) initiatives, activities, guidelines and policies related to the management of human resources, staff morale and recognition; and b) the general enhancement of a Programme culture based upon trust, mutual respect and professional integrity.

- **Subcommittee on Administration (PMC-A)** - to advise on administrative initiatives, activities, guidelines and policies.

- **Subcommittee of Senior Assistants (PMC-SAT)** - to advise on issues related to senior assistants' functions and activities.

## 13.2 ADVISORY COMMITTEE ON MANAGEMENT (ACM)

The Advisory Committee on Management, composed of senior representatives drawn from over twenty stakeholder groups served by the Programme, provides an objective sounding board on policy and operational issues related to the management of the Therapeutic Products Programme. The Committee provides advice in areas such as regulatory policy, cost-recovery, strategic and operational planning, performance standards and performance, continuous quality improvement activities and other Programme management initiatives.

## 13.3 EXPERT ADVISORY COMMITTEES (EAC)

Advisory Committees, composed of experts drawn from the branches of science and medicine relevant to the work of the TPP, have been established to advise and act as sounding boards for the Programme's management and scientists. Consumer representatives also sit on these Committees. There are six EACs at this point:

**New Active Substances** - to provide on-going and timely medical, scientific and clinical advice on current and emerging issues respecting new active substances. The Committee will fulfil its mandate by advising on specific questions raised by the Therapeutic Products Programme. Questions will be issue related, and will focus on difficult risk/benefit evaluations. The Committee may be asked to advise on the following:

- Emerging issues related to efficacy and safety, clinically relevant interactions, and research needed to support regulatory decisions, as required;
- Positioning new drug therapies in the continuum of treatment modalities;
- The development of guidelines in various therapeutic areas;
- Scientific, (pharmacologic, pharmacokinetic, toxicologic) and clinical matters in the assessment of new therapies and products, the application of existing products for new indications, and new dosing regimens in different patient populations;
- Action to be taken during crisis or emergency situations;
- Other safety, efficacy and ethical issues involving the use of marketed drugs.

**Nonprescription Drug Regulation** - to provide the Therapeutic Products Programme with on-going and timely expert advice on specific questions of benefit and risk management with respect to the use of nonprescription medications by Canadians. Without limiting the foregoing, the Committee could be asked to advise on the following:

- The change in status of a prescription drug to nonprescription and vice versa;
- The safety of a nonprescription product or ingredient or category of ingredients;
- The labelling requirements for a product or ingredient or category of ingredients;
- The assessment of information on adverse drug reactions and drug interactions;
- Responses during critical situations concerning the safety of a product or ingredient;
- Ethical questions in respect of non-prescription drugs.

**Pharmacovigilance** - to provide on-going and timely medical and scientific advice on current and emerging issues related to post-approval drug surveillance. Without limiting the foregoing, responsibilities of the Committee will include the following:

- Evaluations of post-approval drug safety, quality, efficacy and effectiveness issues;
- Assessments of adverse drug reaction (ADR) reports, including causality assessments, of drug product complaints, failures and anomalies, and recommendations regarding actions to be taken;
- Assessments of drug safety issues related to drug misuse, abuse or off-label use, and recommendations regarding actions to be taken;
- Identification of post-approval drug safety, quality, efficacy and effectiveness issues for investigation and evaluation;
- Recommendations of topics for the Canadian ADR Newsletter and of the publication of case reports, their risk/benefit evaluations, and recommendations and communications arising from EAC meetings, that are deemed appropriate for medical or scientific journals;
- Recommendations for pharmacoepidemiological or other research to be commissioned by the Therapeutic Products Programme or by its partners or stakeholders; and
- Recommendations for educational programs or other interventions designed to enhance professional and consumer awareness of post-approval drug safety, quality, efficacy, and effectiveness issues.

**HIV Therapies** - to provide the Therapeutic Products Programme with on-going and timely medical, scientific and clinical advice on current and emerging issues related to HIV therapies and vaccines; specific HIV-AIDS-related products (pre- and post-market); and HIV-AIDS research developments in Canada and internationally. Without limiting the foregoing, the Committee could be asked to advise on the following:

- Development of guidelines for use of HIV therapies, as required;
- Emerging issues related to efficacy/effectiveness, biological and chemical analytical methods, toxicity, clinically relevant interactions of therapies, and necessary regulatory research, as required;
- Post-marketing requirements of new drugs, as needed;

- Positioning new drug therapies into the continuum of care for public health associations;
- Ethical and policy issues regarding drug approval and use, and on the regulatory approval process in general;
- Scientific, pharmacological, toxicological and clinical expert advice in the development of protocols for Investigational New Drugs, guidelines for submission review, and in the review of drug/biological submissions, as required;
- An assessment of new therapies and products, the application of existing products for new indications, and new dosing regimens in different patient populations.

**Blood Regulation** - to provide the Programme with on-going and timely medical, scientific, ethical and communications advice on current and emerging issues concerning: the regulation of the Canadian blood system; the manufacture, distribution and use of blood, blood components and blood products ("blood"); standards and procedures including prospects for international harmonization; developments in Canada and internationally; and public disclosure of information. Without limiting the foregoing, the Committee will carry out its mandate by advising on the following, as requested:

- Development of regulations and guidelines for the collection and manufacture of blood and its use;
- Medical, pharmacological, toxicological and clinical issues in the development of study protocols and in the review of blood submissions;
- Pre- and post-marketing requirements including inspections and licensing;
- International harmonization of standards and procedures;
- Emerging scientific issues related to quality and safety such as chemical and biological methods, the use of blood products obtained by biotechnology (e.g., recombinant blood factors) and necessary regulatory research;
- Ethical and policy issues respecting blood and the public disclosure of information available to manufacturers and to Health Canada; and
- Responses during real or perceived crises or emergency situations.

**Complementary Medicines** - to provide the **Therapeutic Products** Programme with timely expert advice questions of benefit and risk management with respect to the use of complementary medicines by Canadians for prescribed and self-medication use. Without limiting the foregoing, the Committee may be asked to advise on the following:

- The acceptability and reliability of published reference sources used to support safety, efficacy and quality evidence;
- The content of a standard ingredient or category of ingredients monograph including the labelling requirements;
- The safety, quality and/or efficacy of a product, or ingredient, or category of ingredients;

- Specific issues related to efficacy, quality and safety, clinically relevant adverse reactions, incidents and interactions, and research needed to support regulatory decisions;
- Responses during critical situations concerning the safety of a product or ingredient; and
- The development of recommendations in various specialty areas including, but not limited to, standards, guidelines and policy.

**APPENDIX**

## DEFINITIONS

Under the Food and Drugs Act,

A "**drug**" includes any substance or mixture of substances manufactured, sold or represented for use in

a) the diagnosis, treatment, mitigation or prevention of disease, disorder or abnormal physical state, or the symptoms thereof, in human or animal,

b) restoring, correcting, or modifying organic functions in human or animal, or

c) disinfection in premises in which food is manufactured, prepared or kept.

A "**device**" means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in

a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof, in man or animal,

b) restoring, correcting, or modifying a body function or the body structure of man or animal,

c) the diagnosis of pregnancy in humans or animals, or

d) the care of humans or animals during pregnancy and at and after birth of the offspring, including care of the offspring

and includes a contraceptive device but does not include a drug.

### Working Definition of a Therapeutic Product:

A **therapeutic product** includes any drug, medical device, blood, tissue, organ, natural health product, nutraceutical, or other substance or article manufactured, sold or represented for therapeutic, diagnostic or preventive use, as described in the definitions of a "drug" or a "device" in the *Food and Drugs Act*.